510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

APR 24 2007

RFA Medical, Inc.
40874 Calido Place
Fremont, CA 94539, USA
Telephone: (650) 776-4804
Fax: (510) 573-3343

B. Contact Person

Nancy Lincé
Regulatory Affairs Consultant
Telephone: (650) 759-6186
Fax: (510) 885-9935

C. Date Prepared

February 9, 2007

D. Device Name

Trade Name:	InCircle™ Bi-Polar RF Ablation System
Classification Name:	Electrosurgical cutting and coagulation device and accessories

E. Performance Standards

The RFA Medical InCircle™ Bi-Polar RF Ablation Device has been designed to comply with the applicable sections of ANSI/AAMI American Standard for Electrosurgical Devices HF-18:2001 and the International Electrotechnical Commission Standard for Electrosurgical Devices IEC 60601-2-2:2006.

F. Device Description

The RFA Medical InCircle™ Bi-Polar RF Ablation System is a sterile, disposable, bi-polar, Radio Frequency (RF), hand-held electrosurgical device that utilizes opposing sets of Electrodes to coagulate/ablate a region of soft tissue using bi-polar RF energy. The device is designed for use in percutaneous, laparoscopic, and intraoperative surgical procedures. The device is designed for use with standard FDA cleared RF generators, such as the Boston Scientific Corporation (RadioTherapeutics) RF3000 (K000241) and the RITA Medical Systems 1500X (K983214).

G. Intended Use

The RFA Medical InCircle™ Bi-Polar RF Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the thermal coagulation of soft tissues.

H. Substantial Equivalence

The RFA Medical InCircle™ Bi-Polar RF Ablation System is substantially equivalent to the Boston Scientific Concerto™ Bipolar Needle Electrode (K040785, K050361, and K060419) and Rita Medical Systems StarBurst™ Xli Electrosurgical Device (K010060). The InCircle has a similar intended use, materials of construction, and principles of operation as the predicate devices. Both the subject and predicate devices are designed to coagulate/ablate tissue by delivering RF energy with the use of electrodes.

I. Summary of Data

Bench testing/functional testing was performed on the RFA Medical InCircle™ Bi-Polar RF Ablation System to ensure that the product is substantially equivalent to the predicate device and to ensure that the new device does not raise new questions of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RFA Medical, Inc.
% KEMA Quality B.V.
Ms. Patricia L. Murphy
4377 County Line Road
Chalfont, Penssylvania 18914

APR 24 2007

Re: K070711
Trade/Device Name: InCircle™ Bi-Polar RF Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 11, 2007
Received: April 12, 2007

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter Rumm

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 070071

Device Name: InCircle™ Bi-Polar RF Ablation System

Indications for Use:

The RFA Medical InCircle™ Bi-Polar RF Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the thermal coagulation of soft tissues.

Prescription Use X **OR** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070071